REMARKS

This communication is responsive to the outstanding Office Action issued July 30, 2002, in connection with the above-identified patent application. Claims 1-3 have been rejected. Claims 4-6 stand withdrawn as directed to a non-elected invention.

The Office Action

The priority claim has been denied has been denied.

The drawings have been objected to.

Claims 1-3 have been rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled by the disclosure.

Claims 1-3 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Priority Claim

Applicants have claimed the benefit of the filing date under 35 U.S.C. §120 of U.S. Provisional Application No. 60/175,005 filed January 7, 2000. Additionally, Applicants have also claimed the benefit of the filing date of U.S. Application Serial No. 09/663,147 filed September 15, 2000, as a continuation-in-part, which ultimately claims priority back to the filing date of U.S. Patent No. 5,660,982, which was filed on October 4, 1994.

The Examiner has denied the Applicants the benefit of the earlier claimed priority dates of both the provisional patent application and the continuation-in-part application. Applicants strenuously object to this denial of priority.

With respect to the entitlement to the provisional application's priority date, Applicants submit that the data presented in Example 4 of the present application was taken from the priority provisional application. Thus those features of the present application find clear support in the priority provisional patent application.

Furthermore, with respect to claiming the benefit of the filing date of U.S. Application Serial No. 09/663,147 (which ultimately goes back to October 4, 1994) as a continuation-in-part, Applicants submit that the present claim language finds

clear support in the original parent applications' disclosure. Specifically, in U.S. Patent No. 5,660,982, which is the ultimate priority document from which the present application claims the benefit as a continuation-in-part, the disclosure provides support for the present claims at, for example, col. 5, lines 13-20.

As such, Applicants believe that support for the invention, as claimed, is clearly found in the claimed priority documents. Acknowledgment of the entitlement to the claimed priority dates is requested.

Objections To The Drawings

The Examiner objected to the drawings as failing to comply with 37 CFR §1.84(p)(5). Specifically, the Examiner pointed out that certain reference numerals on the drawings were not found in the specification.

In response thereto, Applicants have amended the specification to correspond with the reference numerals on the drawings. As such, withdrawal of the objection is requested.

The Rejections Under 35 U.S.C. §112

The Examiner rejected claims 1-3 under 35 U.S.C. §112, first paragraph, as claiming an invention which is not fully described in the specification. Basically, the Examiner's position is that the disclosure fails to support what is being claimed.

Initially, and without conceding to the appropriateness of the rejection, Applicants have amended the claims to recite that the antibodies are against the γ2-domain III chain of laminin-5. In addition, the claims were further amended to recite that the exposure of carcinoma cells to the antibodies against the γ2-domain III chain of laminin-5 inhibits cell migration. Support for these amendments can be found at page 5, lines 13-20, and in Example 4, in particular, at page 35, line 22 through page 36, line 11.

With respect to whether or not the disclosure provides enablement with respect to how the invention works, the Examiner is pointed to Example 4 of the disclosure, in particular to page 30, lines 1-22 relating to production of antibodies.

page 31, lines 12-31 relating to the migration assay and page 32, lines 30-32 through page 41. In particular, at page 35, line 22 through page 36, line 11, the method for inhibiting cell migration using antibodies against the γ2-domain III chain of laminin-5 is disclosed.

In view of the arguments presented above and the amendments to the claims, Applications submit that the written description clearly supports the claimed invention. Withdrawal of the rejection is respectfully requested.

The Examiner then issued a similar rejection of claims 1-3 under 35 U.S.C. §112, first paragraph, indicating that the specification is not enabled for the claimed method. In particular, the Examiner again seems concerned with there not being any description of the antibodies along with there being no examples of the claimed method.

Applicants submit that the previous arguments set forth above with respect to the initial rejection under 35 U.S.C. §112, first paragraph are applicable here as well.

Specifically, the claims have been amended to recite that cell migration of invasive carcinomas can be inhibited by exposure of said cells to antibodies against the γ2-domain III chain of laminin-5. This is clearly shown at page 35 as described above.

In view of the evidence provided in the specification, and in particular that provided in Example 4, Applicants submit that a person skilled in the art would be enabled to practice the invention without undue experimentation. Enablement is not precluded by the necessity for some experimentation such as routine screening [of hydridomal cells]. *See In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). It is not required that the application describe the claim limitations in greater detail than the invention warrants. The description must be sufficiently clear that persons of skill in the art will recognize that the applicant made the invention having those limitations. *Martin v. Mayer*, 823 F.2d 500, 3 USPQ 2d 1333 (Fed. Cir. 1987).

In the present application, the claim language is clearly supported by the disclosure, especially Example 4 which shows inhibiting migration of cancerous

cells by exposure to an antibody against the γ2-domain III chain of laminin-5. As such, Applicants submit that a person skilled in the art, upon reading the disclosure of the present application, would readily ascertain what the invention is and how to practice the invention without undue experimentation. Withdrawal of the rejection is therefore respectfully requested.

Finally, the Examiner rejected claims 1-3 under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner was concerned with the phrase "biological activity".

Without conceding to the appropriateness of the rejection, Applicants have amended the claims to remove the term "biological activity". As such, the rejection is deemed moot. Withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

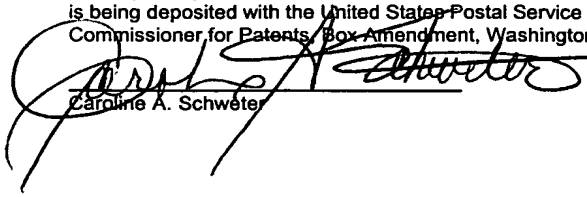
Applicants believe this communication to be fully responsive to the outstanding rejection. Reconsideration and withdrawal of the rejections and notification of allowability are earnestly solicited. The Examiner is encouraged to contact the undersigned should any issues remain.

Respectfully submitted,
FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

Richard J. Minnich (Reg. No. 24,175)
Brian G. Bembenick (Reg. No. 41,463)
1100 Superior Avenue, Seventh Floor
Cleveland, Ohio 44114-2518
216/861-5582

CERTIFICATE OF MAILING

I hereby certify that this **Amendment and Response Under 37 CFR §1.111** in connection with Application Serial No. 09/756,071 is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Box Amendment, Washington, D.C. 20231 on October 30, 2002.



Caroline A. Schweter

VERSION OF SPECIFICATION AND AMENDED CLAIMS TO SHOW MARKINGS MADE

In the Specification:

FIG. 2A-[D]G shows *in situ* hybridization for γ-2 chain mRNA on sections of ductal mammary carcinoma (2A), malignant melanoma (2B), squamous cell carcinoma of the skin [(2C-2D)], (2C, 2D) and squamous cell carcinoma of the vulva (2E-2G). Magnification: 2C x 100, all others x 640. Photos marked by plain letter [ie.] i.e., X, show *in situ* hybridization results for γ–2 chain mRNA on stained sections. Photos marked by the [apostrophe] letter -1, [ie.] i.e., X-1, are the dark field images of the respective photomicographs.

FIGS. 3A, A-1 is incisionally wounded mouse skin (72 hours after wounding) showing signal for γ-2 chain in keratinocytes at the leading edge of the migrating epithelium (curved arrow). Magnification: x 640. FIG. 3A is a photo of *in situ* hybridization on a stained section showing γ-2 chain signal. FIG. 3A[']-1 is a photo showing the dark field image of 3A.

FIGS. 4A-[B]D shows the nucleic acid sequence for the γ-2 chain cDNA and the derived amino acid sequence. FIG. 4A-4C is the full cDNA for the 5,200 base pair sequence, available from EMB/GenBank/DDBJ under the accession number Z15008. FIGURE 4[B]D is the nucleotide and derived amino acid sequence of the alternative 3' end sequence from cDNA clones providing a sequence of 4,316 base pairs, [availible] available from EMB/GenBank/DDBJ under the accession number Z15009. (Kallunki, et al., 1992, supra.) SEQ ID NOs: 12, 13, 14, and 15.

In the Claims:

Claim 1 has been amended as follows:

1. (Twice Amended) A method for intervention of γ2 chain interactions of invasive carcinomas with surrounding tissues by [using anti-γ2-chain] exposing an invasive carcinoma to antibodies [to inhibit the γ2-chain biological activity of said invasive carcinomas] against the γ2-domain III chain of laminin-5.

The following new claims 7, 8, 9, 10 and 11, have been added:

7. (New) The method of claim 1 wherein said exposure of invasive carcinomas to the antibody against the γ2-domain III chain of laminin-5 is *in vitro*.

8. (New) The method of claim 1 wherein said exposure of invasive carcinoma to the antibody against the γ2-domain III chain of laminin-5 is *in vivo*.

9. (New) The method of claim 1 wherein cells of the invasive carcinoma are inhibited from migrating upon exposure to the antibody against the γ2-domain III chain of laminin-5.

10. (New) The method of claim 9 wherein the antibody is monoclonal.

11. (New) The method of claim 9 wherein the antibody is polyclonal.